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FABRICATION METHOD OF ORAL CARE COMPOSITION

By

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BACKGROUND OF THE INVENTION

The present invention relates to an oral care composition applicable to oral hygiene products such as toothpaste and mouth detergent. More particularly, the present invention relates to a fabrication method of an oral care composition by use of salt and herbal extracts for treatment efficacy on periodontal diseases.

Oral care products including dentifrice are known to contain components such as sodium chlorides, antiplasmin agents, allantoin derivatives, vitamines, amino acids and others. Since the selection of the components is substantially influenced by target taste, target flavor and target sweetness, the sodium chloride which is known as effective in oral hygiene has suffered from artificial deformation in composition when used for different products. For example, a peppermint oil and a spearmint oil are used as a flavoring agent to decrease salty taste. Or sodium lauryl sulphate is used as a foaming agent to improve foaming properties. Also, tranexamic acid, aluminium chlorohydroxy allantonate and tocopherol acetate in admixture with sodium chloride are used to

treat or prevent periodontal diseases. However, no treatment or prevention effects against periodontal diseases are expected other than slight improvements in taste and flavor. US Patent No. 5,180,575 discloses a bamboo-salt as a composition for oral care products such as toothpaste. Still, treatment or prevention effects against periodontal disease are hardly expected.

In consideration of the foregoing disadvantages, the present inventor has conducted extensive clinical experiments on the combination of salt and herbal extracts for substantial improvement on prevention or treatment effects against periodontal disease while enhancing oral hygiene. Although it took a considerable time period to compare treatment or prevention effects from experimental herbs which are widely being used in oriental herbal treatments, it was eventually discovered that a *Cimicifuga*-salt preferably in admixture of *Coptis* and zanthoxylin produces substantial treatment effects against periodontal diseases such as gingivitis or dental caries.

A *Cimicifuga*-salt consists of a living salt and *Cimicifuga* extracts. The living salt is obtained by melting pure bay salt at a high temperature or preferably at about 1,000 °C for about 48 hours. The living salt is believed to have treatment effect since it reserves

condensed energy and osmotic pressure at the melting stage which substantially enhance sterilization effects. Also, it has treatment effects against gum bleeding, edema, inflammation, halitosis, tooth decay and serious periodontal diseases (Donguebogam, Korean Medicinal Book). The nostrum of the living salt is further demonstrated in Sinkum (Living Salt) Therapy for Healthy Life and Living Salt Therapy Sink (by Kyound Jin Park, 1985), and Living Salt Diet for Diabetics, Folklore Living Salt Therapy to Revive Liver Cells (by Il Sun Oh, 1993). The living salt has been used by Oriental doctors specialized in alternative medicine for hundreds of years in Korea.

Commercially available *Cimicifuga* herb contains cimitin $C_{20}H_{34}O_7$, Et_2O, BuOH, cimicifugin, salicylic acid, cimigenol, 25-O-methylcimigenol-3-xyloside, cimigol, dahurinol, isodahurinol, acerinol, 24-O-acetylacerinol, cimicifugoside, cimicifugenin, 26-O-methylcimifugoside, ciminifugenin A, 26-O-methylcimifugenin A, cimifugenol, friedelin, b-sitosterol, khellol, amminol, 3,4-dimethylcinnamic acid, ferulic acid, iso-ferulic acid, dahurinol, coumarin and others. The *Cimicifuga* herb alleviates pain and inhibits the growth of tuberculosis viruses and dermal fungi in vitro. In the human body, Et_2O serves as sedatives and suppresses edema. BuOH reduces

bodily temperature and serves as pain relievers, edema suppressants, and anti-ulceratives.

Consequently, it is understood that the *Cimicifuga*-salt obtained by combining the living salt and *Cimicifuga* extracts is effective for detoxication, fever reduction, anti-inflammation, improvement in the cytoginic function, snti-sepsis, cancer prevention, sterilization, cold symtoms, various anemisa, and hypotension.

Coptis herb is commerically available and includes alkaloid, berberine (4-7%), *Coptis*ine, jatoerrhizine, palmitine, magnoflorine, ferulic acid and others. In pharmacological actions, the *Coptis* herb relieves bodily fever, prevents dehydration and toxication. Among the components, the berberine and *Coptis*ine are known to serve as antibiotics, laxatives, anti-inflammatory agents and stytics, and stop diarrhea.

Commercially available zanthoxylin is classified to belong to zanthoxylum piperitum and contains sanshool $C_{16}H_{27}ON$, sanshoon $C_{16}H_{25}ON$, sanshoamide, geraniol and others. Zanthoxylin serves to warm bodily digestive organs, relieve pain, treat diarrhea and kill intestinal worms. In vitro, it suppresses gram-negatives such as dysentery viruses, and gram-positive aerobic viruses such as staphylococcus aureus and it also kills round worms in swine.

So it is readily understood that the *Cimicifuga*-salt alone or in admixture of *Coptis* and zanthoxylin enhances treatment or prevention effect against periodontal diseases such as gingivitis, dental caries, oral abscess, gum inflammation, tooth decay and other gum or tooth related diseases.

SUMMARY OF THE INVENTION

The present invention is contrived to overcome the disadvantages in the prior arts. Therefore, it is an object of the present invention to provide a fabrication method of an oral care composition which substantially improves treatment efficacy on periodontal diseases by using a combination of salt and herbal extracts.

To achieve the above-described object, the fabrication method of an oral care composition according to the present invention comprises the steps of drying a *Cimicifuga* root, soaking the dried *Cimicifuga* root in a vinegar for a predetermined time period, and drying the vinegar-soaked *Cimicifuga* root. The vinegar-soaked then dried *Cimicifuga* root, a salt and a water are admixed at a sequential weight ratio of about 10% to 40%, about 10% to 40% and about 30% to 50%. Then, the admixture of the *Cimicifuga* root, the salt and the water are evaporated to obtain a *Cimicifuga*-salt concentration.

For a better version, *Cimicifuga* root fibers are removed from the *Cimicifuga*-salt concentration. Preferably, each step for fabricating the oral care composition is performed within a non-metallic container. The vinegar is a fermentation from a brown rice. A filler material including a sodium chloride may be added to the *Cimicifuga*-salt concentration. The oral care composition may be is one selected from a toothpaste, a mouth detergent, a mouthwash, a chewing gum, and a gum massage cream.

In an embodiment, a dried *Coptis* root is further included in the fabrication steps so that the dried *Cimicifuga* root and the dried *Coptis* root are admixed at a substantially equivalent ratio in weight. Said each dried *Cimicifuga* root and *Coptis* root are soaked in a vinegar for a predetermined time period and then dried. The vinegar-soaked and then dried *Cimicifuga-Coptis* root admixture, a salt and a water at a sequential weight ratio of about 10% to 40%, about 10% to 40% and about 30% to 50%. The admixture of the *Cimicifuga-Coptis* root admixture, the salt and the water are evaporated to obtain a *Cimicifuga-Coptis*-salt concentration. *Cimicifuga* root fibers are removed from the *Cimicifuga-Coptis*-salt concentration.

As another embodiment, an oral care composition comprises a *Cimicifuga* root and a *Coptis* root each substantially dried, soaked in a vinegar, and then dried for a predetermined time period. The dried, vinegar-soaked and then dried *Cimicifuga* root and *Coptis* root are formed at a substantially equivalent ratio in weight. Further comprised for the oral care composition is a salt and a water so that the dried, vinegar-soaked and then dried *Cimicifuga-Coptis* root, the salt and the water are admixed at a sequential weight ratio of about 10% to 40%, about 10% to 40% and about 30% to 50%. The admixture is evaporated to a *Cimicifuga*-salt concentration, wherein *Cimicifuga* root fibers are removed from the *Cimicifuga*-salt concentration to form the oral care composition.

The advantages of the present invention are numerous in that (1) the fabrication method of an oral care composition enables *Cimicifuga* and *Coptis* extracts to directly apply to interior of a user's mouth together with nostrum living salt in a daily required formulation such as toothpaste, thereby enhancing prevention or treatment effects against periodontal diseases; (2) the oral care composition allows oriental herbal therapeutic treatment to get effectively mixed with daily hygienic activities such as oral cleansing as an alternative to dentist-allergic periodontal patients; and (3) the oral

care composition effectively prevents mouth diseases to serve as a reliable alternative therapy against mouth cancer which is ranked the 8th highest death rate among the U.S. cancer patients.

Although the present invention is briefly summarized, the fuller understanding of the invention can be obtained by the following drawings, detailed description and appended claims.

THE DETAILED SPECIFICATION OF THE PREFERRED EMBODIMENTS

A fabrication method of an oral care composition according to the present invention comprises the steps of drying a *Cimicifuga* root, soaking the dried *Cimicifuga* root in a vinegar for a predetermined time period, and then drying the vinegar-soaked *Cimicifuga* root. Here, the *Cimicifuga* root is better harvested in September and October. The harvested *Cimicifuga* root is cleaned using a cold water, preferably a running cold water as an initial hygienic process. The vinegar may be a fermentation from a brown rice. Selectively, the vinegar may be diluted depending on a required degree of sterilization.

The vinegar-soaked then dried *Cimicifuga* root, a salt and a water are admixed at a sequential weight ratio of about 10% to 40%, about 10% to 40% and about 30% to 50%. Then, the admixture of the *Cimicifuga* root, the salt

and the water are evaporated to obtain a *Cimicifuga*-salt concentration. Thereafter, *Cimicifuga* root fibers are removed from the *Cimicifuga*-salt concentration. Alternately, the sequential weight ratio of the vinegar-soaked then dried *Cimicifuga* root, the salt and the water may be about 40%, about 30%, and about 30%.

Each step for the oral care composition fabrication is performed within a non-metallic container to better preserve original ingredients in the *Cimicifuga* root. Also, each drying step is better performed on an oak panel layered over a heated floor. The heated floor is prepared by red soil. Here, it is preferred that the oak panel is about 1.0 centimeter in thickness. The temperature for each drying step may be about 55 Celsius degrees to prevent fungus generation and at the same time fully take advantage of hygienic performance in oak itself. Each drying step is implemented for at least one week or about 170 hours.

In a preferred embodiment, a filler material is added to the *Cimicifuga*-salt concentration. The filler material substantially includes a sodium chloride. The thusly constituted composition may be one selected from a toothpaste, a mouth detergent, a mouthwash, a chewing gum, and a gum massage cream.

For a better performance, a fabrication method of an oral care composition comprising the steps of drying a *Cimicifuga* root and a *Coptis* root, admixing the dried *Cimicifuga* root and the dried *Coptis* root at a substantially equivalent ratio in weight, soaking said each dried *Cimicifuga* and *Coptis* root in a vinegar for a predetermined time period, drying the vinegar-soaked *Cimicifuga-Coptis* root admixture, and admixing the vinegar-soaked then dried *Cimicifuga-Coptis* root admixture, a salt and a water at a sequential weight ratio of about 10% to 40%, about 10% to 40% and about 30% to 50%. The admixture of the *Cimicifuga-Coptis* root admixture, the salt and the water are then evaporated to obtain a *Cimicifuga-Coptis*-salt concentration. Then, *Cimicifuga* root fibers are removed from the *Cimicifuga-Coptis*-salt concentration.

The sequential weight ratio of the vinegar-soaked then dried *Cimicifuga-Coptis* root, the salt and the water is about 40%, about 30%, and about 30%. Alternately, the sequential weight ratio of the vinegar-soaked then dried *Cimicifuga-Coptis* root, the salt and the water is about 20%, about 40%, and about 40%.

In another embodiment, an oral care composition is fabricated according to the method as disclosed above. That is, the oral care composition according to the

present invention comprises a *Cimicifuga* root and a *Coptis* root each substantially dried, soaked in a vinegar, and then dried for a predetermined time period, wherein the dried, vinegar-soaked and then dried *Cimicifuga* root and *Coptis* root are formed at a substantially equivalent ratio in weight. The composition further comprises a salt and a water so that the dried, vinegar-soaked and then dried *Cimicifuga-Coptis* root, the salt and the water are admixed at a sequential weight ratio of about 10% to 40%, about 10% to 40% and about 30% to 50%. The admixture is evaporated to a *Cimicifuga*-salt concentration, and *Cimicifuga* root fibers are removed from the *Cimicifuga*-salt concentration to form the oral care composition.

According to the composition, the vinegar-soaked then dried *Cimicifuga* root, the salt and the water is about 40%, about 30%, and about 30%. Alternately, the vinegar-soaked then dried *Cimicifuga* root, the salt and the water is about 20%, about 40%, and about 40%. The vinegar is preferably obtained by a fermentation from a brown rice.

The salt required for the oral care composition is a living salt obtained by melting a pure bay salt at about 1000 °C for about 24 hours. The composition solely including the *Cimicifuga*-salt may further comprise foaming agents, wetting agents, sweetening agents,

flavoring agents, polishing agents, preservatives, binders and pharmacologically active agents. Alternately, the composition may comprise solely the admixture of the *Cimicifuga*-salt, the *Coptis*, and the zanthoxylin. The composition solely including the *Cimicifuga*-salt, *Coptis* and zanthoxylin may further comprise foaming agents, wetting agents, sweetening agents, flavoring agents, polishing agents, preservatives, binders and pharmacologically active agents.

The oral care composition according to the present invention may be incorporated in oral hygiene products such as a toothpaste, a mouth detergent, a tooth powder, a mouth spray, a chewing gum, a gum massage cream, or a denture cleansing formulation. Here, the composition of a *Cimicifuga*-salt alone or in admixture of *Coptis* and zanthoxylin is also called Byczenol (a trademark to be registered by the inventor).

To obtain the best performance, it is recommended that the composition of the *Cimicifuga*-salt alone or in admixture of *Coptis* and zanthoxylin account for about 30% in a classic toothpaste. Selectively, the composition rate can be raised up to 80% for a stronger treatment effect against periodontal diseases. However, the ratio or amount of *Cimicifuga*-salt along or in admixture of

Coptis and zanthoxylin may be adjusted depending upon treatment or prevention targets.

An effective amount of components for a conventional toothpaste may be mixed with the composition according to the present invention. For example, there are polishing agents such as dicalcium, phosphate, silicone dioxide aluminum hydroxide, or calcium carbonate; humectants such as sorbitol, glycerin, or polyethylene glycol; foaming agents such as sodium alkylsulphate, or polyoxyethylene-polyoxypropylene condensation polymer; sweetening agent such as saccharin, or aspartame; flavoring agents such as peppermint oil, or spearmint; preservatives such as methyl paraoxy benzoic acid; therapeutic agents such as sodium fluoride, chlorhexidine, tranexamic acid, or allantoin; binders; and others.

The oral care composition according to the present invention will be further described with reference to the accompanying Examples and Comparative Examples.

COMPARATIVE EXAMPLES 1 TO 4 AND EXAMPLES A, B

Toothpaste components were prepared as shown in Table 1

Table 1

Components	Comparative Examples				Examples	
	1(%)	2(%)	3(%)	4(%)	A(%)	B(%)
Byczenol-A*	-	-	-	-	10.0	20.0
Dicalcium phosphate	40.0	40.0	40.0	40.0	30.0	20.0
Non-crystalline sorbitol solution	25.0	25.0	25.0	25.0	15.0	15.0
Bamboo-salt	2.0	5.0	-	-	-	-
Sodium chloride	-	-	1.0	1.5	-	-
Aluminum chlorohydroxy allantoinate	-	-	0.1	0.1	-	-
Tocopherol acetate	-	-	0.1	0.1	-	-
Tranexamic acid	-	-	0.1	0.1	-	-
Sodium glutamate	-	-	0.01	0.01	-	-
Sodium alkylsulphate	2.0	2.0	2.0	2.0	-	-
Sodium saccharin	1.0	1.0	1.0	1.0	-	-
Sodium carboxymethyl cellulose	1.0	1.0	1.0	1.0	-	-
Flavoring agent	0.8	0.8	0.8	0.8	-	-
By adding diluted water, up to	100	100	100	100	100	100
U.V. spectrophotometer transmittance	20.0	30.0	10.0	10.0	50.0	70.0

* Byczenol-A is *Cimicifuga*-salt

COMPARATIVE EXAMPLES 5 TO 8 AND EXAMPLES C TO F

Toothpaste components were prepared as shown in Table 2

Table 2

Components	Comparative Examples (%)				Examples (%)			
	5(%)	6(%)	7(%)	8(%)	C(%)	D(%)	E(%)	F(%)
Byczenol-B*	-	-	-	-	25.0	40.0	55.0	70.0
Dicalcium phosphate	35.0	35.0	35.0	23.0	-	-	-	-
Calcium carbonate	-	-	-	-	-	-	-	-
Precipitated silica	-	-	-	-	-	-	-	-
Anhydrous silicic acid	-	-	-	-	-	-	-	-
Non-crystalline sorbitol solution	-	-	-	-	-	-	-	-
Sorbitol solution	-	-	-	-	-	-	-	-
Glycerin	-	-	-	-	35.0	30.0	20.0	15.0
Sodium chloride	10.0	-	-	-	-	-	-	-
Bamboo-salt	0.5	5.0	10.0	30.0	-	-	-	-
Tranexamic acid	0.05	0.05	0.05	0.05	-	-	-	-
Aluminum chlorohydroxy allantoinate	0.1	0.1	0.1	0.1	-	-	-	-
Tocopherol acetate	0.1	0.1	0.1	0.1	-	-	-	-
5-amino caproic acid	0.05	0.05	0.05	0.05	-	-	-	-
Sodium alkysulphate	2.0	2.0	2.0	2.0	-	-	-	-
Sugar-fatty acid ester	-	-	-	-	-	-	-	-
N-acyl glutamate	-	-	-	-	-	-	-	-
Magnesium chloride	0.05	0.05	0.1	0.05	-	-	-	-
Trimagnesium phosphate	0.05	0.05	0.05	0.05	-	-	-	-
Sodium saccharin	0.1	0.1	0.1	0.1	-	-	-	-
Methyl Paraben	0.05	0.05	0.05	0.05	-	-	-	-
Sodium carboxymethyl Cellulose	0.8	0.8	0.8	0.6	-	-	-	-

Flavoring agent	0.1	0.1	0.1	0.1	-	-	-	-
By adding diluted water, up to	100	100	100	100	100	100	100	100

* Byczenol-B is *Cimicifuga*-salt admixed with *Coptis* and zanthoxylin

EXPERIMENTAL TEST AND RESULTS THEREOF

Several groups of thirty (30) persons (between age 20 and age 55) suffering from halitosis (1st group) , teeth sour (2nd group), gum bleeding (3rd group), gingivitis (4th group) and toothache (5th group) were tested three times a day for fifteen (15) days. The thirty participants brushed their teeth for about three minutes each time during the test period. The first group of thirty persons used the toothpastes containing the composition according to the present invention. The second group of the other thirty persons used conventional tooth pastes as described in the above Comparative Examples. The test results are as shown in Table 3.

Table 3

		No. of Healed Persons per 30 Participants (%)				
Toothpaste Examples	Byczenol ratio	I*	II*	III*	IV*	V*

	Example C	25%	25	26	25	26	26
			(83.3)	(86.7)	(83.3)	(86.7)	(86.7)
	Example D	40%	26	27	27	27	27
			(86.7)	(90.0)	(90.0)	(90.0)	(90.0)
	Example E	55%	28	29	28	28	28
			(93.3)	(96.7)	(93.3)	(93.3)	(93.3)
	Example F	70%	29	30	29	29	29
			(96.7)	(100.0)	(96.7)	(96.7)	(96.7)
	Comp. 3	0%	1	3	2	2	3
			(3.3)	(10.0)	(6.7)	(6.7)	(10.0)
	Comp. 4	0%	0	2	1	3	2
			(0.0)	(6.7)	(3.3)	(10.0)	(6.7)
	Comp. 5	0%	2	0	0	2	1
			(6.7)	(0.0)	(0.0)	(6.7)	(3.3)
	Comp. 6	0%	2	0	1	2	1
			(6.7)	(0.0)	(3.3)	(6.7)	(3.3)

*Type of Participants Healed by Toothpaste Treatment

I: : participants with haliosis

II: participants with teeth sour

III: participants with gum bleeding

IV: participants with gingivitis

V: participants with toothache

Table 3 demonstrates treatment effects of the toothpaste containing the oral care composition according to the present invention. As shown therein, the weight of

the *Cimicifuga*-salt alone or in admixture of *Coptis* and zanthoxylin (Byczenol) is preferred to account for about 25% to 70% of a toothpaste of conventional components.

Example G

Mouth Detergent

Ethanol (90%)	20.0%
Glycerine (98%)	10.0%
Polyxyethylene-polyoxypropylene Copolymer	1.0%
Tranexamic acid	0.05%
Byczenol	10.0%
Sodium saccharin	01%
Flavoring agent	1.0%
By adding distilled water up to	100.0.%

Example H

Mouthwash

Sodium bicarbonate	20.0%
Stannic acid	18.0%
Sodium sareosinate-coconut oil	5.0%
Sodium lauryl sulfate	5.0%

Benzalkonium chloride	2.0%
EDTA	5.0%
Sodium tripolyphosphate	14.0%
Polyethylene glycol	2.0%
Byczenol	24.0%
Flavoring agent	5.0%

Example I

Chewing gum

Gum base	15.0%
Sorbitol	30.0%
Manniol	12.0%
Glycerine	13.0%
Lecithin	0.5%
Sweetening agent	2.0%
Byczenol	26.0%
Flavoring agent	1.5%

Example J

Gum Massage Cream

Glycerol monolaurate	3.0%
Oleic alcohlate	5.0%
Polyethylene glycol	15.0%
White Vaseline	3.0%
Monosodium N-palmitic glutamate	5.0%
Hydroxyethyl cellulose	5.0%

Tocopherol acetate	0.1%
Byczenol	10.0%
Sweetening agent	0.2%
Aluminum chlorohydroxy allantoinate	3.0%
Flavoring agent	0.3%
By adding distilled water up to	100.0%

As demonstrated above, the oral care composition according to the present invention prevents or treats periodontal diseases in a reliable healing rate.

An advantage of the present invention is to enable *Cimicifuga* and *Coptis* extracts to directly apply to interior of a user's mouth together with nostrum living salt in a daily required formulation such as toothpaste, thereby enhancing prevention or treatment effects against periodontal diseases. Further, the oral care composition allows oriental herbal therapeutic treatment to get effectively mixed with daily hygienic activities such as oral cleansing as an alternative to dentist-allergic periodontal patients. In addition, the oral care composition effectively prevents mouth diseases to serve as a reliable alternative therapy against mouth cancer which is ranked the 8th highest death rate among the U.S. cancer patients.

Although the invention has been described in considerable detail with reference to certain preferred

versions thereof, other versions are possible by converting the aforementioned construction. Therefore, the scope of the invention shall not be limited by the specification specified above and the appended claims.